

REMARKS

In the Office Action, restriction to one of two groups of inventions is required under 35 U.S.C. § 121; Claims 15 and 18 are rejected under 35 U.S.C. § 112, second paragraph; Claims 1, 4, 5, 8, 12, 14, 15 and 20 are rejected under 35 U.S.C. § 102; and Claims 2, 3, 6, 7, 9-11, 13, 16-19, and 21-28 are rejected under 35 U.S.C. § 103. Claims 15 and 18 have been amended; and claims 29-32 have been cancelled. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned **“Version with Markings to Show Changes Made.”** Applicants respectfully submit that the rejections have been overcome or are improper in view of the amendments for the reasons set forth below.

At the outset, the Patent Office requires a restriction to one of two groups of the invention: Group I (Claims 1-28); and Group II (Claims 29-32). During a telephone conversation with Mr. Robert M. Barrett, undersigned attorney of record, on September 30, 2002, a provisional election was made without traverse to prosecute the invention of Group I, Claims 1-28. The Patent Office requires that affirmation of this election be made in reply to the Office Action.

In response, Applicants elect without traverse Group I (Claims 1-28). As previously discussed, Claims 29-32 have been cancelled. Applicants reserve the right to file a divisional application directed to the non-elected invention including Claims 29-32. In view of same, Applicants believe they have been responsive to the restriction requirement.

In the Office Action, Claims 15 and 18 are rejected under 35 U.S.C. § 112, second paragraph. In response, Claims 15 and 18 have been amended as previously discussed. Applicants believe that amended Claims 15 and 18 fully comply with 35 U.S.C. § 112. Further, Applicants note for the record that the changes made to Claims 15 and 18 regarding same have been made for clarification purposes and thus do not have a narrowing effect on the scope of the claimed subject matter.

Accordingly, Applicants respectfully request that the rejection of Claims 15 and 18 under 35 U.S.C. § 112 be withdrawn.

In the Office Action, Claims 1, 4, 5, 8, 12, 14, 15 and 20 are rejected under 35 U.S.C. § 102 in view of U.S. Patent No. 4,201,673 (“Kanno”). Applicants believe that this rejection is improper as detailed below.

Of the pending claims at issue, Claims 1 and 12 are the sole independent claims. Claim 1 relates to a dialyzer inlet header that includes a body designed to be attached to an end of a dialyzer; an inlet channel that provides fluid communication from an exterior of the dialyzer to an interior of the dialyzer wherein the inlet channel defines a fluid flow path that is axial to a fiber bundle located in the interior of the dialyzer. The dialyzer inlet header further includes at least one member for modifying the fluid flow path of fluid as it exits the inlet channel.

Independent Claim 12 relates to a dialyzer. The dialyzer includes a body; a fiber bundle located in an interior of the body; a blood inlet located at a first end of the body that includes a fluid flow channel that causes blood to flow in an axial direction with respect to the fiber bundle; and a member located in juxtaposition to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle.

Applicants have discovered that the improved header design of the present invention can provide an improved flow of blood into the interior of the dialyzer and specifically to the fiber bundle. This eliminates, or at least substantially reduces, the zones of low flow thereby reducing the potential for clotting while improving the ability to rinse the header of blood. See, Specification, page 2, lines 15-20.

In contrast, Applicants believe that the *Kanno* reference is deficient with respect to a number of features of the claimed invention. For example, nowhere does the *Kanno* reference disclose the modifying member features of independent Claims of 1 and 12 contrary to the Patent Office's position. Indeed, the alleged modifying member (27) of *Kanno* is disposed in the annular rib (15) portion of the dialyzer housing in the midst of the hollow fibers (19). The member (27) therefore pushes the fibers (19) onto the inner periphery of the annular rib (15). In other words, the member (27) secures the fibers (19) to the inner periphery of the annular rib (15). See, *Kanno*, col. 4, lines 40-46.

This clearly contrasts the claimed invention. As previously discussed, the claimed invention relates to improved headers that can provide improved flow of blood into the interior of the dialyzer and specifically to the fiber bundle. Claim 1 relates to a dialyzer inlet header that includes, in part, at least one member for modifying the fluid flow path of a fluid as it exits the inlet channel. Claim 12 recites a dialyzer that includes, in part, a blood inlet and a member located in juxtaposition to the blood inlet that causes blood to flow to a perimeter region of a first end of the fiber bundle. Again, the alleged modifying member of *Kanno* is located in the annular

rib portion of a dialyzer in the midst of the hollow fibers and, thus is not a part of the dialyzer header in contrast to the claimed invention. For at least these reasons, Applicants believe that the *Kanno* reference fails to anticipate the claimed invention.

Accordingly, Applicants respectfully request that the anticipation rejection be withdrawn.

In the Office Action, Claims 2, 3, 6, 7, 9-11, 13, 16-19 and 21-28 are rejected under 35 U.S.C. § 103. In particular, Claims 2, 6, 9-11, 13, 16-19 and 21-26 are rejected in view of *Kanno* and further in view of U.S. Patent No. 6,053,967 ("*Heilmann*"); and Claims 3, 7, 27 and 28 are rejected in view of *Kanno* and further in view of *Heilmann* and U.S. Patent No. 5,830,370 ("*Maloney Jr.*"). Applicants believe that these rejections are improper as discussed below.

At the outset, the *Kanno* reference is clearly deficient with respect to the claimed invention. As previously discussed, *Kanno* at least fails to disclose or suggest the modifying member features as required by independent claims 1 and 12, let alone the plurality of members of a dialyzer header that impart a circular motion to the fluid as it enters the interior of the header as required by independent claim 21. As previously discussed, the clear focus of *Kanno* relates to modifications in an annular rib portion of a dialyzer to facilitate blood flow through the dialyzer and not to the header as required by the claimed invention.

Claims 1, 12 and 21 are the sole pending independent claims and thus Applicants respectfully submit that *Kanno* is clearly deficient with respect to the respective dependent claims at least for substantially the same reasons. Further, *Kanno* at least fails to disclose a curved channel as required by Claims 6 and 16, a plurality of curved vanes extending from a portion of the body of the header as required by Claims 2, 10, 11, 13, 18, 19, 22 and 23, a disk located under an exit opening of the inlet fluid channel as required by Claims 9, 17, 24 and 25, and a plurality of vanes that impart a circular motion as required by Claim 21 as even admitted by the Patent Office.

Further, Applicants do not believe that the *Heilmann* reference can be relied on to remedy the deficiencies of *Kanno*. At the outset, Applicants question whether the teachings of *Kanno* or *Heilmann* can be combined in the first place. Of course, "[o]bviousness cannot be established by combining the teaching of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined only if there is some suggestion or incentive to do so. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 USPQ 929, 932, 933 (Fed. Cir. 1984).

As previously discussed, the clear emphasis of the *Kanno* reference relates to modifying the annular rib region of the dialyzer to facilitate flow therethrough. The *Heilmann* reference relates to a device that is designed to separate gas from fluid flowing therethrough. The *Heilmann* device includes a flow-deflection component in an inlet region to facilitate this process. See, *Heilmann*, col. 4, lines 18-24. Thus, what incentive would either of *Kanno* or *Heilmann* provide one skilled in the art to modify the header of *Kanno* based on the air separator device design disclosed in *Heilmann* in order to facilitate flow through a dialyzer?

Even if combinable, Applicants believe that *Kanno* and *Heilmann* are clearly deficient with respect to the claimed invention. As previously discussed, *Kanno* merely discloses a supporting member (27) located in an annular rib (15) of the dialyzer in the midst of the fibers, and thus at least fails to disclose or suggest a dialyzer header that is designed to facilitate blood flow through a dialyzer as required by the claimed invention.

The clear emphasis of *Heilmann* relates to an air separator as discussed above. This seeks to solve a completely different problem than what the claimed invention seeks to solve. As disclosed in *Heilmann*, the inflowing blood or the other liquid to be degassed passes through the inlet 16 and flows through the flow-deflection channels 36, as a result of which the flow direction is deflected in a spatially wound curve out of the direction initially running parallel to the longitudinal axis (11) into a direction running tangentially against the wall (14) of the chamber. A helical flow is thereby induced, with the circular movement elements building up a pressure difference, the result of which is that air bubbles are driven in a direction of the longitudinal axis and, because of their lower density, climb upwards. The risen air bubbles form, in an upper part of the chamber 12, an air cushion 38 which can be removed through a suitable ventilation bore. See, *Heilmann*, column 4, line 66 to column 5, line 11.

This clearly contrasts the claimed invention that provides improved dialyzer headers designed to increase blood flow in the perimeter region of the dialyzer header space where low flows are suspected, thus reducing the potential for clot formation. In this regard, the fluid flow modifying member of the dialyzer header of the present invention can act to modify the blood flow as it transitions from an axial flow in the inlet channel to a radial flow along the top interior of the header surface. This allows the blood to remain in motion, thus preventing stagnant zones to form in the perimeter region. Additionally, the improved flow patterns of the claimed invention can provide a more complete cleaning of blood during rinse back. Based on at least

these differences, Applicants believe that one skilled in the art viewing *Heilmann* would not be inclined to modify *Kanno* to arrive at the claimed invention.

Moreover, Applicants do not believe that the Patent Office can rely solely on *Maloney Jr.* to remedy the deficiencies of *Kanno* and *Heilmann*, even if combinable. What the Patent Office clearly has done, in hindsight, is simply to piece together the cited references by selectively picking and choosing teachings of each in an attempt to explain what the claimed invention discloses. This is clearly improper. Of course, the Court of Appeals for the Federal Circuit has criticized this motivation to combine analysis as being "hindsight reconstructive" because the motivation to combine the references was first disclosed in the present invention. *In re O'Farrell*, 853 F.2d 894, 902, 903 (Fed. Cir. 1988).

For at least these reasons, Applicants believe that the cited art fails to disclose or suggest a number of features of the claimed invention. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request the obviousness rejections be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend Claims 15 and 18 as follows:

15. (Amended) The dialyzer of Claim 12 wherein the ~~header~~blood inlet is sealed to an end of the dialyzer body.

18. (Amended) The dialyzer ~~inlet header~~ of Claim 17 wherein the member includes a plurality of curved vanes.

Claims 29-32 have been cancelled without prejudice or disclaimer.